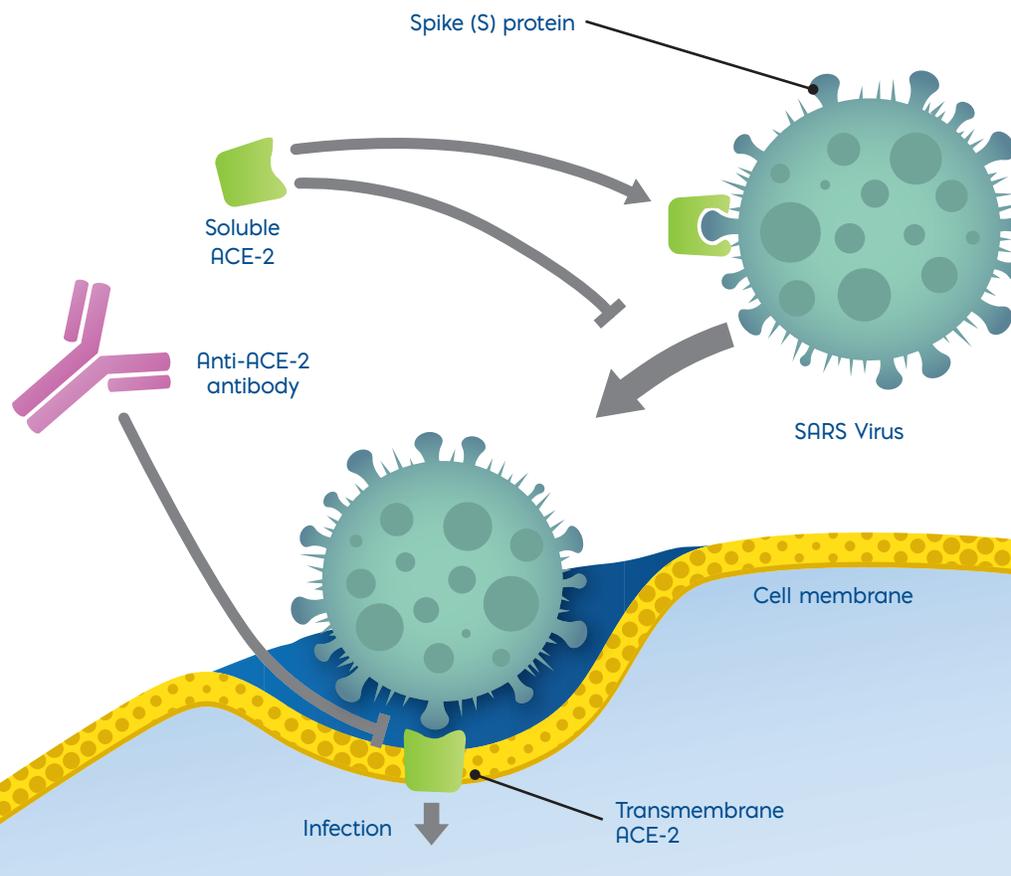


COVID-19

Reagents Solutions for Molecular and Immunology SARS-CoV-2 Diagnostic Assays

The key to fighting the COVID-19 pandemic is through diagnostic testing. By identifying infectious individuals, it is possible to trace the pathogen's spread and stop the chain of transmission. Research labs are racing to develop innovative testing methods to overcome the bottlenecks which are creating challenges to conducting widespread testing.

Viral tests for COVID-19 that diagnose an acute infection rely on the detection SARS-CoV-2 nucleic acid or antigen using nasopharyngeal swabs. Assays that could use alternative sample types such as saliva or nasal swabs and could be collected by an individual, are highly sought after as they would be simpler and quicker to use as well as being safer for healthcare workers. Overall challenges such as shortages in the reagents required for RNA extraction have created bottlenecks and many labs are searching solutions that provide flexibility in the face of these shortages such as the development of extraction-free assays. Antigen detection assays should help expand COVID-19 testing capacity and more rapid, point-of-care assays are expected to be launched into the market to help quickly scale up the testing of millions of individuals.

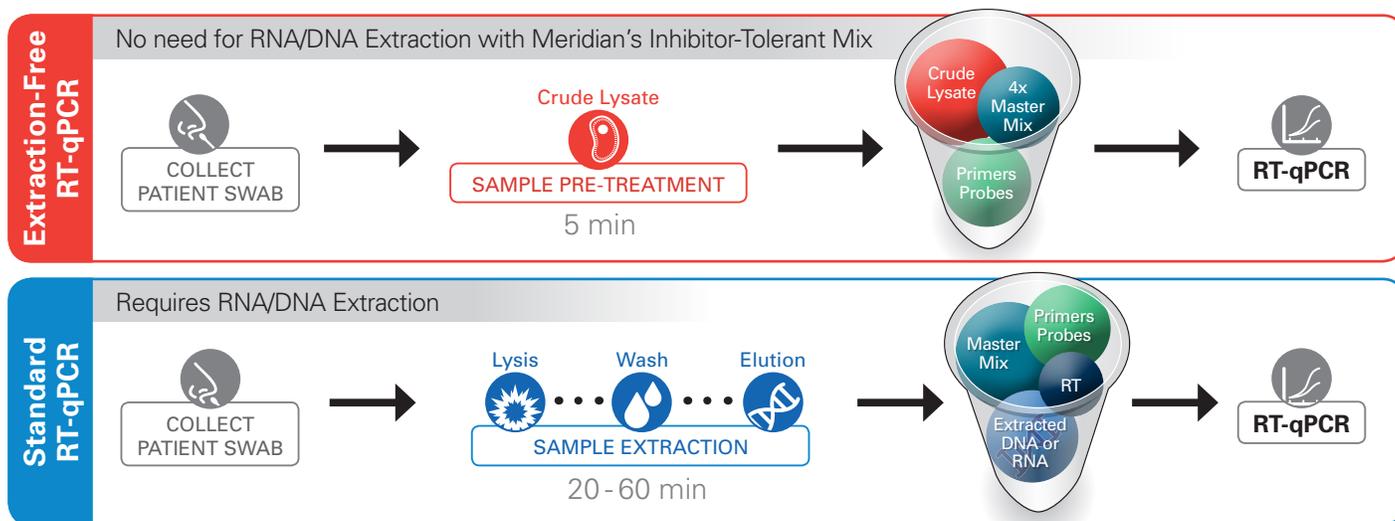


Molecular Reagents

Optimized RT-qPCR Mixes

Meridian's portfolio of RT-qPCR master mixes have been designed to simplify the development of SARS-CoV-2 molecular assays and enable new features such as extraction-free amplification. Each master mix contains a hot-start polymerase, dNTPs, buffer and other components optimized for each particular application (e.g. lyophilization). Only primers and probes are required to complete the assay formula.

SARS-CoV-2 requires an RNA extraction step which is time limiting step and can result in RNA being lost during the extraction process reducing the performance of the assay. However, extraction is typically required to remove inhibitors which would otherwise impact an assay's sensitivity and accuracy. In order to address this challenge, Meridian has developed an Inhibitor-Tolerant RT-qPCR Mix capable of delivering sensitive multiplex detection, even in the presence of difficult inhibitors found in sputum, saliva and stool specimens. This new mix offers a novel alternative to nucleic acids extraction, saving both time and labor which are vitally important in viral screening assays that require rapid detection for infection control.

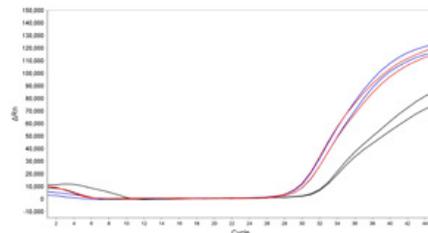


Product Data

Inhibitor-Tolerant RT-qPCR Mix exhibits a high tolerance to PCR inhibitors from clinical samples

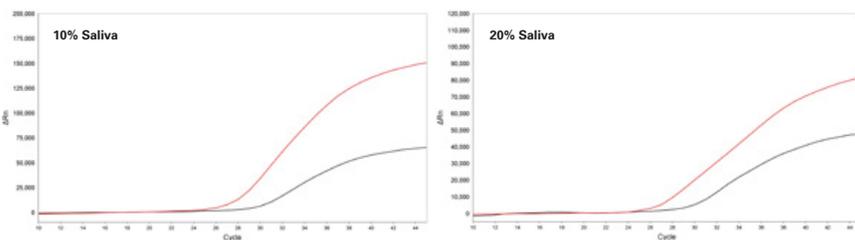
SPUTUM SPECIMENS

Amplification profile of inactivated influenza virus spiked into samples containing 5% sputum or no sputum. The data illustrates that the performance of Inhibitor-Tolerant RT-qPCR Mix (MDX016) in the presence of 5% artificial sputum (red) is the same as Fast One-Step RT-qPCR Mix (MDX032) with no sputum (blue). In contrast, the sensitivity and performance of Fast One-Step RT-qPCR Mix (MDX032) significantly decreases in the presence of 5% artificial sputum (black) compared to no sputum or compared to Inhibitor-Tolerant RT-qPCR Mix (MDX016) with sputum.



SALIVA SPECIMENS

MDX016 (red) and MDX032 (black) amplification traces of Influenza A spike in presence of saliva swabs (COPAN ESwab 359C) at 10% (left) and 20% (right) final concentration. With earlier Ct (approx. 4 Ct) and higher fluorescence (approx. +50%), the results demonstrate the superiority of Inhibitor-Tolerant RT-qPCR Mix (MDX016) against a standard RT-qPCR Mix (MDX032) for the detection of viral RNA in presence of saliva swab resuspension in UTM.



Product Selection Chart



Inhibitor-Tolerant RT-qPCR Mix

Optimized for extraction-free assays from crude clinical specimens (sputum, saliva and stool)



Fast 1-Step RT-qPCR Mix

Ideal for multiplex assays on fast, automated high-throughput systems



Low LOD 1-Step RT-qPCR Mix

Designed for multiplex detection of viruses for applications such as blood bank testing



Lyo-Ready 1-Step RT-qPCR Mix

Pre-formulated with lyo-excipients for lyophilization into beads or cakes

Features

Cat#	MDX016	MDX032	MDX025	MDX024
Concentration	4x	2x	2x	2x
Presentation	Single-tube mix	3 tubes (<i>Polymerase, Reverse Transcriptase, RNase Inhibitor</i>)	Single tube mix	3 tubes (<i>Polymerase, Reverse Transcriptase, RNase Inhibitor</i>)
Master Mix	✓	✓	✓	✓
Hot-Start	Antibody	Antibody	Antibody	Antibody
Ambient-Temperature Assays	-	-	-	★
Multiplex Reactions	★	★	★	★
RNA/DNA Extraction-free protocols	★	-	-	-
Contains dUTP	-	-	★	-

RT-qPCR Control

RT-qPCR Extraction Control

- Monitors assay inhibition
- Suitable for use with inhibitor-rich samples

MDX028 (Red, Quasar 670)
MDX029 (Orange, Cal Fluor Orange)

VLP RNA Extraction Control

- Closely mimics the test sample
- Undergoes the same processing from lysis and extraction to detection

MDX068 (Red, Cy5)
MDX069 (Orange, HEX)
MDX071 (Custom)

VLP RNA Extraction Control

- Compatible with lyophilization for creating freeze-dried mixes

MDX068 (Red, Cy5)
MDX069 (Orange, HEX)
MDX071 (Custom)

★ Recommended



SARS-CoV-2 High Sensitivity Antibodies

For Rapid Antigen Detection Assays

Rapid antigen tests can provide a result in minutes and can be produced at a lower cost in large scales. However, the performance of a rapid antigen test is limited by the sensitivity of the antibodies used. Meridian's monoclonal antibodies are highly sensitive for the detection of SARS-CoV-2 and they do not cross-react with seasonal coronavirus strains. They are ideal for developing reliable and sensitive rapid lateral flow antigen assays for the detection of active COVID-19 infections.

TRIMERIC SPIKE ANTIBODIES

- ✓ For use in lateral flow antigen detection COVID-19 assays
- ✓ Designed to work on saliva samples (no lysis required)
- ✓ Novel antibody pair to the trimeric form of the Spike 1 surface glycoprotein, recognizes both the G614 and D614G strains
- ✓ Using a mixture of detection antibodies Cat# 9565 and #9551 in a 1:1 ratio creates a synergistic effect that increases assay sensitivity in ELISA
- ✓ Recognizes a linear epitope - binding is not conformation-dependent
- ✓ Sensitivity of approx. 300 pg/mL in ELISA
- ✓ Does not cross-react with SARS-CoV, HCoV-229E, HCoV-HKU1, HCoV-NL63 and HCoV-OC43

Capture Antibody:

Cat# 9550 MAb to SARS-CoV-2 S1 (Trimeric)

Detection Antibody:

Cat# 9551 MAb to SARS-CoV-2 S1 (Trimeric)

Cat# 9565 MAb to SARS-CoV-2 S1 (Trimeric)

*9551 and 9565 can be used together in a 1:1 ratio to increase assay sensitivity in ELISA

NUCLEOCAPSID ANTIBODIES

- ✓ For use in lateral flow antigen detection COVID-19 assays
- ✓ Highly sensitive antibody pair currently used in commercial diagnostic kits worldwide (LOD: 2.87×10^3 TCID₅₀/mL, heat-inactivated culture fluid)
- ✓ Manufactured in multigram quantities weekly
- ✓ No cross-reaction with other respiratory pathogens, e.g., MERS-Coronavirus, Human Coronavirus (NL63, 229E and OC43), Influenza A, Influenza B, Respiratory Syncytial Virus (RSV) (A and B), Streptococcus A, Mycoplasma, Human Adenovirus (Types 1, 3, 5, 7, 8, 11, 18, and 23), Human Parainfluenza Virus (Types 1, 2, 3 and 4), Human Rhinovirus (Types 1, 14 and 42) and Human Metapneumovirus

Capture Antibody:

Cat# 9548 MAb to SARS-CoV-2 NP

*pairs with both detection antibodies 9547 and 9549

Detection Antibody:

Cat# 9547 MAb to SARS-CoV-2 NP

Cat# 9548 MAb to SARS-CoV-2 NP

SARS-CoV-2 Recombinant Antigens

For Serology Antibody Assays

Serologic tests are an important tool for monitoring the evolution of an outbreak. Specifically, IgG/IgM antibody tests are essential for identifying previously undiagnosed infections in the asymptomatic population. Meridian's recombinant antigens are expressed in human mammalian cells and insect cells using proprietary expression and purification technologies. Expression in either human or insect cells provides for post-translational modifications such as glycosylation and phosphorylation which can offer significant performance advantages over *E. coli* expressed formats.

Insect-Cell Expressed:

Cat# 9556 Spike Protein, S1 Subunit, His-tag

Cat# 9557 Spike Protein, N-terminal Domain (NTD) S1 Subunit, His-tag

Cat# 9558 Spike Protein, Receptor Binding Domain (RBD) S1 Subunit, His-tag

Cat# 9560 Nucleocapsid Protein, His-tag

HEK293 Expressed:

Cat# 9552 Spike Protein, Receptor Binding Domain (RBD) S1 Subunit, His-tag

Cat# 9555 Human ACE2 Protein, Fc1 tag

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